

### **REMARKS**

Applicants thank the Examiner for the thorough examination given the present application.

### **Status of the Claims**

Claims 11-28 will be pending in the above-identified application upon entry of the present amendment. Claims 1-10 have been cancelled herein. Claims 11-28 have been added. Support for new claims 11-12 can be found in claims 1 and 7 as well as in the present specification, *inter alia*, at page 5, lines 9-10. Support for new claims 13-14 can be found in claim 2. Support for new claims 15-19 can be found in the examples of the present specification. Support for new claims 20-21 and 26-28 can be found in claims 4 and 7. Support for new claims 22-23 can be found in claim 5. Support for new claims 24-25 can be found in claim 6. Thus, no new matter has been added. Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

### **Examiner's Interview**

Applicants would like to thank the Examiner for his time during the interview on May 13, 2009. Applicants appreciate the courtesies extended to them in this application. During the interview, the Examiner indicated that method claims 20-28 appeared to be allowable pending an updated search. After the updated search, should the method claims still be considered allowable and product claims 11-19 not be considered allowable, Applicants authorize the cancellation of product claims 11-19 while preserving their rights to file a divisional application on the product claims at a later date. Applicants believe that the claims are now in condition for allowance. Should the Examiner believe that there remains any outstanding issues, Applicants respectfully request that the Examiner contact Applicants' Representative so as to expedite resolution of these outstanding issues, via an Examiner's Amendment or the like.

**Issues under 35 U.S.C. § 103(a)**

The Examiner has rejected claims 1-10 under 35 U.S.C. § 103(a) as being unpatentable over Johnson '160 (US 2003/0195160) in view of Tanimoto et al. '732 (US 5,447,732) and Yalpani '612 (US 2004/0063612).

Claims 1-10 have been cancelled herein, which renders the outstanding rejection moot. Applicants have newly added claims 11-28 in an effort to further define the scope of protection owed to Applicants. Applicants respectfully submit that claims 11-28 are allowable since the cited references do not disclose each and every element of the pending claims. Specifically, Applicants respectfully assert that at least method claims 20-28 are allowable as indicated by the Examiner pending an updated search. As such, Applicants respectfully assert that claims 11-28 clearly define over the cited references, and an early action to this effect is earnestly solicited.

To the extent the outstanding rejection applies to the currently pending claims, Applicants respectfully traverse. Reconsideration and withdrawal of the outstanding rejection are respectfully requested based on the following considerations.

**Legal Standard for Determining Prima Facie Obviousness**

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

*Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Exemplary rationales that may support a conclusion of obviousness include:

- (a) combining prior art elements according to known methods to yield predictable results;
- (b) simple substitution of one known element for another to obtain predictable results;
- (c) use of known technique to improve similar devices (methods, or products) in the same way;
- (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (e) “obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
- (f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* MPEP 2143.03.

#### Distinctions over the Cited References

Independent claims 11-12 recite, *inter alia*, “polyglutamic acid...or a salt thereof...as the sole active ingredient in an amount effective to treat xerostomia.” Claims 26-27 contain a similar element.

In stark contrast, Johnson ‘160 is directed to the use of the compound of formula (I) and potentially polyglutamic acid for the treatment of xerostomia. As such, Johnson ‘160 fails to disclose polyglutamic acid as the ***sole active*** ingredient. In fact, Johnson ‘160 discloses that the pharmaceutically acceptable salts are salts that ***retain or enhance the desired biological activity of the compound of Formula (I)*** (paragraph [0162]; emphasis added). Thus, Johnson ‘160 only discloses that the compound of Formula (I) is used for the treatment of xerostomia (see claim 65).

In this regard, Johnson '160 does not describe that the organic salts formed with polyglutamic acid is effective for treating dry mouth. Johnson '160 does not disclose nor teach that the polyglutamic acid or the specific salt thereof *per se* promotes salivary secretion and produces moisturizing effect. From the disclosure of Johnson '160, it is not expected that polyglutamic acid *per se* has excellent sialogogue effect. As described above, Johnson '160 only discloses that the compound of Formula (I) is used for the treatment of xerostomia. Thus, Johnson '160 fails to disclose ***a method of treating xerostomia comprising administering a composition comprising polyglutamic acid or a salt thereof*** as recited in independent claims 20-21.

Thus, Johnson '160 does not disclose each and every aspect of claims 11-12 and 20-21 as well as those claims dependent thereon. Applicants respectfully submit that Tanimoto et al. '732 and Yalpani '612 do not overcome the deficiencies of this reference.

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Johnson '160 in view of Tanimoto et al. '732 and Yalpani '612 fail to disclose all of the claim limitations of independent claims 11-12 and 20-21, and those claims dependent thereon. Accordingly, the combination of references does not render the present invention obvious. Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

#### **Issues under 35 U.S.C. § 112, second paragraph**

The Examiner has rejected claims 1-10 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse in view of the new claims.

First, the Examiner asserts that the phrase “having an average molecular weight of 10,000 to 5,000,000” is unclear without a measurement. Claims 1-10 have been cancelled herein. However, to the extent that the new claims recite this phrase, the claims also recite that the measurement is in Daltons. As such, Applicants respectfully request that the rejection be removed.

Second, the Examiner asserts that the phrase “is 0.001 to 10% by weight” is unclear when the percentage is not recited against another amount. Claims 1-10 have been cancelled herein. However, to the extent that the new claims recite this phrase, the claims also recite that the percentage is based on the total weight of the composition. As such, Applicants respectfully request that the rejection be removed.

**CONCLUSION**

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case clearly indicating that each of claims 11-28 are allowed and patentable under the provisions of title 35 of the United States Code.

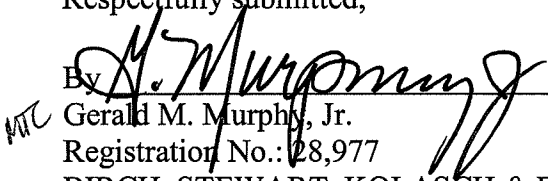
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Monique T. Cole, Reg. No. 60,154 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By

  
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